

### REMARKS

Claims 1-4 and 21-24 are amended and under consideration. Claim 18 is cancelled.

Claims 1-4 and 21-24 were rejected under 35 U.S.C. 102(e) as being anticipated by Carlson et al. (U.S. 6,140,065), for the reasons that the disclosure of Carlson meets the limitations of the steps set forth in the generic claims and the apparatus of Carlson meets all the limitations of the generic apparatus of the present application.

In response, Applicant submits that the unamended claims in question had read upon the generic claims of Carlson. However, the amended claims 1 and 21 and the claims depending on them, include critical limitations – 1) that outside operator may not bypass the algorithm, and 2) that the clinical tests to be done are determined by the apparatus automatically and do not require an operator to add data such as age, etc. In other words, the amended claims are allowable over Carlson.

Claims 1-4, 18 and 21-24 were rejected under 35 U.S.C. 102(b) as being anticipated by Adlassnig et al. (1995), for disclosing the HEPAXPERT-I computer algorithm which is alleged to meet the limitations of the generic apparatus claims, as memory, a processor and software.

In response, Applicant agrees that the unamended claims 1-4, 18 and 21-24 were anticipated by Adlassnig et al. (1995). However, the amended claims 1 and 21 and claims dependent on them, now include distinguishing elements, as explained above for overcoming Carlson and, now Adlassnig et al.

Also, claims 1-4, 18 and 21-24 were rejected under 35 U.S.C. 102(a) as being anticipated by Pearlman et al. (1998) for disclosing Figure 2 a diagnostic algorithm for the diagnosis of HBV.

The Action stated that Pearlman et al. has a differing inventive entity than the instant invention, and has an earlier publication date than the filing date of the instant invention.

In response, Applicant agrees that the unamended claims 1-4, 18 and 21-24 were anticipated by Pearlman et al. However, the amended claims 1 and 21 and claims dependent on them are not anticipated by Pearlman et al. In fact, Pearlman et al. does not in any way disclose that the algorithm for HBV is not subject to an outsider's control. Therefore, based on the amendments submitted herein, all pending claims under consideration should be allowed.

In any event, E. Pearlman in Pearlman et al. and the sole inventor in this application are one and the same inventive entity. Moreover, Pearlman et al. was published in July/August 1998, and the filing date of this application is within less than one year from this publication, i.e., April 30, 1999.

Therefore, there is no basis for any of the rejections made in the Action and pending claims 1-4 and 21-24 should be allowed. In addition, upon allowance of these generic claims, Applicant requests that claims 5-11, 13-17, 19 and 20 be reinstated as being drawn to non-elected species, which was the condition of the Restriction Requirement.

If for any reason, however, the Examiner should deem that this application is not in condition for allowance, the Examiner is respectfully requested to telephone the undersigned attorney.

Respectfully submitted,

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CLEAN VERSION OF CLAIM AMENDMENTS UNDER 37 C.F.R. 1.121

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1. (Twice Amended) A method of pipelining a disease-specific diagnostic algorithm to achieve a cost-effective and accurate diagnosis, said method comprising the steps of:

- a) classifying the various subgroups of the disease, said subgroups being classified based on pathology, pathogenic agent, cause or symptoms, on an n-bit data word stored in a memory;
- b) defining the clinical tests suitable for confirming the diagnosis of each of the subgroups classified in a);
- c) selecting to run only the clinical tests listed in b) for the sub-group showing an abnormality thereby not allowing unnecessary clinical tests to be carried out in duplicate or to be ordered by an outside operator, and comparing the result obtained with the normal value provided on the n-bit data word;
- d) sequentially running the relevant clinical test of each of the sub-groups upon receiving a first of said clinical test values, and computing the next set of said clinical test for further testing, and
- e) repeating steps c) and d) until a complete diagnosis of the specific disease type and group is provided, thereby avoiding unnecessary clinical tests and expensive duplicative procedures, while enabling an accurate diagnosis using the disease-specific diagnostic algorithm.

21. (Twice Amended) An apparatus for pipelining a diagnostic algorithm on an n-bit data word, said apparatus comprising:

- a) a memory storing component, said component used for storing the n-bit data words relevant to a set of m clinical tests;
- b) means for sequentially reading out each of a m clinical tests of the n-bit data from said memory such that only said clinical tests are run thereby not allowing unnecessary duplication of tests or unauthorized tests to be ordered by an outside operator, wherein m is an integer greater than one; and
- c) a processor for sequentially programming each of the m clinical tests to produce a complete diagnosis, and for outputting the result.



**MARKED UP COPY OF CLAIM AMENDMENTS UNDER 37 C.F.R. 1.121**

1. (Amended) A method of pipelining a disease-specific diagnostic algorithm to achieve a cost-effective and accurate diagnosis, said method comprising the steps of:
  - a) classifying the various subgroups of the disease, said subgroups being classified based on pathology, pathogenic agent, cause or symptoms, on an n-bit data word stored in a memory;
  - b) defining the clinical tests suitable for confirming the diagnosis of each of the subgroups classified in a);
  - c) selecting to run only the clinical tests listed in b) for the sub-group showing some abnormality thereby not allowing unnecessary clinical tests to be carried out in duplicate or to be ordered by an outside operator, and comparing the result with the normal value provided on the n-bit data word;
  - d) sequentially running the relevant clinical test of each of the sub-groups upon receiving a first of said clinical test values, and computing the next set of said clinical test for further testing, and
  - e) repeating steps c) and d) until a complete diagnosis of the specific disease type and group is provided, thereby avoiding unnecessary clinical tests and expensive duplicative procedures, while enabling an accurate diagnosis using the disease-specific diagnostic algorithm.

[18. (Amended) The method according to claim 1, said method comprising the steps of:

- a) defining the clinical tests used for the diagnosis of hepatitis B, including HBsAg, HBsAb or SGPT;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory;
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include HBsAg(+), HBsAg(-)/HBsAb(+) or HBsAg(-)/HBsAb(-), and the next set of said clinical tests includes AFP/HBeAg/Ab, Immune or Hepatitis B(-) respectively,
- e) receiving a next one of said clinical test of said data word, wherein the next of said clinical tests includes "Is HBe Ab present?".
- f) computing a next portion of the diagnostic algorithm using said next of said clinical tests and a most recently calculated value of a computation of a prior portion of the diagnostic algorithm to produce a second clinical test value; and

- g) if necessary, repeating steps (e) and (f) until all of said clinical tests of the data word have been processed, wherein the final value computed for the last clinical test is a value for the complete diagnosis of hepatitis B.]

21. (Amended) An apparatus for pipelining a diagnostic algorithm on an n-bit data word, said apparatus comprising:

- a) a memory storing component, said component used for storing the n-bit data words relevant to a set of m clinical tests;
- b) means for sequentially reading out each of a m clinical tests of the n-bit data from said memory, such that only said clinical tests are run thereby not allowing unnecessary duplication of tests or unauthorized tests to be ordered by an outside operator, wherein m is an integer greater than one; and
- c) a processor for sequentially programming each of the m clinical tests to produce a complete diagnosis, and for outputting the result.





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